

REMARKS

Status of the Claims

Claims 1-7 and 9-20 are pending, with claims 1, 7, and 14 being independent. In order to expedite prosecution, claim 8 has been cancelled herein without prejudice to or disclaimer of the subject matter contained therein and claims 1 and 4 have been amended to even more clearly recite and distinctly claim particularly preferred embodiments of the present invention. Support for the amendments may be found throughout the specification, including, in the original claims. Therefore, no new matter has been added herein.

Initially, Applicants would like to thank the Examiner for indicating that claim 14 contains allowable subject matter.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments, the following remarks, and the attached article.

Priority Document

Applicants respectfully submit that the certified translation was filed with the first submission under 35 U.S.C. § 371 filed on December 22, 2005. A copy of the certified translation is attached hereto for the Examiner's reference. Applicants respectfully submit that a copy of the priority document should be in the PCT application file.

Accordingly, Applicants respectfully request that the priority date be properly recognized. If anything further is required in this regard, Applicants request that the Examiner contact the undersigned.

Rejections under 35 U.S.C. § 101

Claim 8 stands rejected under 35 U.S.C. § 101 for recitation of a use. In order to expedite prosecution, claim 8 has been cancelled without prejudice to or disclaimer of the subject matter contained therein.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 4, and 8 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Specifically, claim 1 stands rejected as lacking a period. In order to expedite prosecution, claim 1 has been amended to insert a period.

Claim 4 stands rejected for recitation of the term “substrates”. Applicants respectfully submit that pharmaceutically acceptable substrates are well understood to be formulation additives, similar to excipients. However, in order to expedite prosecution, claim 4 has been amended to delete the term substrate without conceding the propriety of the rejection.

Claim 8 stands rejected for providing for the use without recitation of any steps. In order to expedite prosecution, claim 8 has been cancelled without prejudice to or disclaimer of the subject matter contained therein.

For at least the above reasons, Applicants respectfully assert that the rejections under 35 U.S.C. §112, second paragraph have been obviated and respectfully request that these rejections be withdrawn.

Rejections under 35 U.S.C. § 102(b), or in the alternative, under 35 U.S.C. . § 103(a)

Claims 2-7 and 9-10 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bergstrand (U.S. Patent No. 5,753,265). Claims 2-7 and 9-13 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Matsuishi (U.S. Patent No. 4,808,596). Claims 1, 3, 11-13 and 15-20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over, Bergstrand and Matsuishi.

Bergstrand discloses the *racemic* mixture of tenatoprazole, (*i.e.*, (±)-5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine). Matsuishi also discloses the *racemic* mixture of tenatoprazole, (*i.e.*, (±)-5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine). Bergstrand and Matsuishi do not disclose or suggest specifically the S-isomer of tenatoprazole.

Applicants respectfully submit that disclosure of a racemate or racemic mixture makes prima facie obvious the separate enantiomers of the racemate; however, such disclosure does *not* anticipate the separate enantiomers. See *Brenner et al. v. LADD, Comr. Pats.*, 147 USPQ 87 (D.C. D.C. 1965) stating that “in the absence of unexpected or

unobvious beneficial properties, an optically active isomer is unpatentable over either the isomer of opposite rotation or, as in this case, the racemic compound itself.”; *In re Adamson et al.*, 275 F.2d 952, 125 USPQ 233 (CCPA 1960); *Sterling Drug Inc. v. Watson*, 135 F.Supp. 173, 108 USPQ 37 (D.C. D.C. 1955); *Emory University v. Glaxo Wellcome Inc.*, 44 USPQ2d 1407 (D.C. N.Ga.); *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1960), and *In re Anthony*, 162 USPQ 594 (CCPA 1969). Accordingly, Applicants respectfully submit that any rejection raised in the Office Action should have been based on obviousness in view of Bergstrand and Matsuishi.

For at least the above-reasons, withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

In response to any obviousness rejections in view of Bergstrand and Matsuishi, Applicants respectfully submit that the (-) enantiomer (i.e., the S-isomer) of tenatoprazole evidences unexpected and unobvious beneficial properties in view of both the racemic compound and the (+) enantiomer. Regarding the unexpected and unobvious beneficial properties of the S-isomer, Applicants submitted a declaration of George Sachs, M.D., D.Sc., pursuant to 35 U.S.C. § 1.132 in U.S. Application Serial No. 10/507,485, now U.S. Patent No. 7,034,038 (a copy of which is attached herewith for the Examiner’s reference). This declaration demonstrates the unexpected and unobvious beneficial properties of S-tenatoprazole.

Moreover, Applicants respectfully submit that the presently claimed monohydrated sodium salt of S-tenatoprazole evidences even further unexpected and unobvious beneficial properties. In this regard, Applicants have attached hereto the article “Characterization of the inhibitory activity of tenatoprazole on the gastric H⁺, K⁺-ATPase in vitro and in vivo”. Applicants note that two of the authors (Homerin and Ficheux) are also inventors of the present application and author Sachs executed the attached declaration.

As provided in the article, (S)-tenatoprazole (free form and the monohydrated sodium salt) provides a prolonged inhibition of acid secretion. Furthermore, as set forth in the article, the pharmacokinetics of the free form and the sodium salt were compared (see pages 844-845). These results demonstrate that the bioavailability of the sodium salt is unexpectedly approximately two-fold greater than the free form (see Table 2, page 845). The results

further demonstrate that the water solubility of the salt is confirmed to be about 65 mg/ml compared to the free form, which is almost insoluble (section 3.4, page 845).

Accordingly, as described in the present application and as demonstrated in the attached article, the presently claimed monohydrated sodium salt of S-tenatoprazole exhibits unexpected and unobvious beneficial properties, including excellent solubility (see specification page 9, lines 25-32 and article section 3.4, page 845), good stability characteristics (see specification page 10, lines 9-18) and a higher bioavailability (see specification page 10-11 and page 12 and article Table 2 page 845).

In view thereof, Applicants respectfully submit that for at least these reasons, the presently claimed monohydrated sodium salt of S-tenatoprazole is non-obvious. Accordingly, Applicants respectfully request that the outstanding rejections under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

Without conceding the propriety of the rejections, the claims have been amended, as provided above, to even more clearly recite and distinctly claim Applicants' invention and to pursue an early allowance. For the reasons noted above, the art of record does not disclose or suggest the inventive concept of the present invention as defined by the claims.

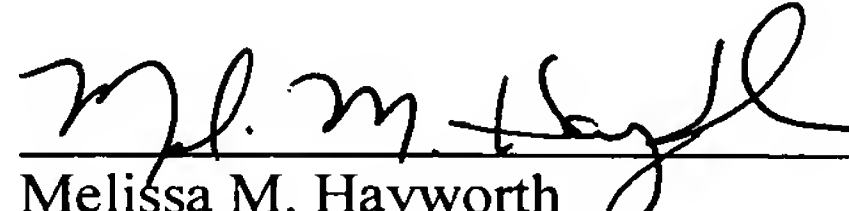
In view of the foregoing remarks, reconsideration of the claims and allowance of the subject application is earnestly solicited. In the event that there are any questions relating to this application, it would be appreciated if the Examiner could telephone the undersigned attorney concerning such arguments so that prosecution of this application may be expedited.

Serial No. 10/561,844
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If necessary to affect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to affect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #1032013-000124).

Respectfully submitted,

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